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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/550,026

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EXAMINER

LUCAS, ZACHARIAH

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/550,026	Applicant(s) MOREIN ET AL.	
	Examiner Zachariah Lucas	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 3, 11, 16, 17 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-10, 12-15, 18 and 20-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/17/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-26 are pending in the application.
2. In the prior action, the Final action of December 17, 2008, claims 1-23 were pending in the application; with claims 3, 11, 16, 17, and 19 withdrawn from consideration; and claims 1, 2, 4-10, 12-15, 18, and 20-23 under consideration are rejected.
3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on June 17 and 18, 2009 have been entered.

In the submission of June 17, the non-entered After-final amendment of May 18, 2009 not be entered; and presented a new set of claim amendments in which claims 1, 7, 8, 13, 14, 22, and 23 were amended; and new claims 24-26 were added.

4. Claims 1, 2, 4-10, 12-15, 18, and 20-26 are under consideration.

Claim Objections

5. **(New Objection)** Claim 26 objected to because of the following informalities: it appears that the claim would more clearly describe the claimed invention by indicating that the composition “provides for enhanced immunogenicity of the liver micro-organism in a host.” Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. **(Prior Rejection- Withdrawn)** Claims 8, 14, 22, and 23 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims were rejected on two grounds.

The first ground of rejection applied to claims 8 and 14. These claims were rejected because it is not clear what is meant by reference to “subfragment A and subfragment C or Quillaja saponin Fraction A.”

The second basis of rejection applied to claims 22 and 23, which were rejected on the basis that it is not clear what is meant by the claim language “wherein a plurality of the iscom particles comprise different Fractions of Quillaja saponin Fraction A.”

In view of the amendments to the claims, the rejection is withdrawn.

Claim Rejections - 35 USC § 102

7. **(Prior Rejection- Withdrawn)** Claims 1, 2, 6, 9, 10, 15, and 21 were rejected under 35 U.S.C. 102(b) as being anticipated by Wechter et al. (U.S. 6,177,081). Applicant’s arguments in traversal are found persuasive. The rejection is therefore withdrawn.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. **(Prior Rejections- Withdrawn)** Claims 1, 2, 5-10, 13-15, and 20-23 were rejected under 35 U.S.C. 103(a) as being unpatentable over Wechter et al. (U.S. 6,177,081) in view of Morein et al. (U.S. 5,679,354). Claims 7, 8, 13, 14, 22 and 23 were rejected under 35 U.S.C. 103(a) as being unpatentable over Wechter in view of Morein as applied above, and further in view of Cox et al. (WO 96/11711). The Applicant's arguments in traversal of these rejections are found persuasive. The rejections are therefore withdrawn.

10. **(Prior Rejection- Restated and Maintained)** Claims 1, 2, 4, 9, 10, 12, 15, and 18 were rejected under 35 U.S.C. 103(a) as being unpatentable over Van Woensel et al. (U.S. 5,925,359). The Applicant traverses this rejection on substantially the same grounds as asserted with respect to the teachings of Wechter above. The argument is not found persuasive with respect to the teachings of Van Woensel. However, the rejection is restated as a rejection of claims 1, 2, 4, 9, 10, 12, 15, 18, and 24-26 over the teachings of Van Woensel in combination with the teachings of Morein et al., (U.S. 5,679,354).

As indicated by the Applicant, those of ordinary skill in the art would not have thought to incorporate a live virus into an ISCOM. However, those of ordinary skill in the art would have known to incorporate individual viral antigens into the adjuvant compositions. As was previously noted, the teaching of Van Woensel suggest the use of immunogenic compositions comprising each of the described live PRRS viruses, and additional antigenic material, such as inactivated viruses, or proteins other antigenic portions thereof. See e.g., claim 8 and 16, and column 5, lines 45-59. Moreover, as was also previously noted, the reference suggests the use of iscoms

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comprising antigens as a means for adjuvanting the antigens. Column 5, lines 14-19. It would therefore have been obvious to those of ordinary skill in the art to have included the indicated additional antigens in an iscom, and to have combined the two antigenic compositions (one comprising the live virus, and one comprising the antigen containing iscoms) into the same composition as suggested by the reference.

Further, while it is noted that the Van Woensel reference does not specifically suggest the inclusion of the viruses in the same composition as an iscom. However, in addition to the teachings of that reference as described above, it is noted that Morein further indicates that particulate compositions comprising saponins may be used as adjuvants by combining them with live viruses. See e.g., column 2, lines 27-42 (specifically suggesting the use of a live virus not incorporated into the saponin containing adjuvant formulation). While Morein indicates that the compositions disclosed therein are not iscoms because the antigenic components are not integrated into the iscom-like structure. Column 1, lines 59-60. However, these teachings indicate that this is the only difference between the iscoms of the art, and those of the Morein reference. Thus, the combined teachings in the art indicate that the saponin containing adjuvant (such as an iscom with no integrated antigens) formulations may be combined with a virus. Thus, even if the teachings of Van Woensel alone would not have provided adequate motivation for the combination of the virus and the saponin containing adjuvant, the additional teachings of Morein would have rendered such a combination obvious.

New claims 25 and 26 provide certain functional requirements of the claimed compositions. As the art suggests the claimed compositions, which meet the structural requirements of claim 9 (the claim from which the new claims depend), the functional limitations

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of the new claims would have been met through making the combination suggested by the prior art. The limitations are therefore not sufficient to distinguish over the teachings of the cited art.

The combined teachings of these references therefore render the claimed invention obvious.

11. **(Prior Rejection- Restated and Maintained)** Claims 5-8, 13, 14, and 20-23 were rejected under 35 U.S.C. 103(a) as being unpatentable over Van Woensel et al. as applied to claims 1, 2, 4, 9, 10, 12, 15, and 18 above, and further in view of Cox et al. (WO 96/11711). The rejection is restated as a rejection of these claims over the teachings of Van Woensel and Morein as applied above, and further in combination with Cox.

The Applicant traverses the rejection on the same basis asserted with respect to the rejection over Van Woensel above. The arguments are not found persuasive for the reasons above. The rejection is therefore maintained for the reasons above, and the reasons of record.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Conclusion

13. No claims are allowed.
14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Haanes et al., (U.S. 5,753,235). This reference teaches the use of recombinant (live) viruses for use as immunogenic agents. See e.g., columns 27-28. The reference suggests the inclusion of adjuvants, including saponin based adjuvants, with such viruses. Column 29, lines 26-50. The reference is therefore considered to provide similar teachings to those of Van Woensel above.
15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is (571)272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Zachariah Lucas/
Primary Examiner, Art Unit 1648